United States General Accounting Office

GAO

Report to the Chairman, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

September 1988

ADP SYSTEMS

FDA Can Reduce Development Risks for Its Import Information System

GAO/IMTEC-88-42

GAO

United States
General Accounting Office
Washington, D.C. 20548

Information Management and
Technology Division

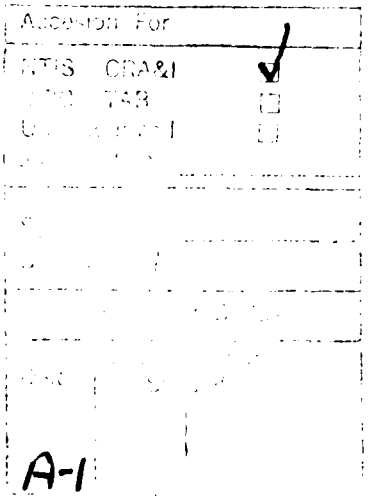
B-228873

September 30, 1988

The Honorable John D. Dingell
Chairman, Subcommittee on Oversight
and Investigations
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

In your August 24, 1987, letter and in subsequent discussions with our office, you requested that we answer four questions about the Food and Drug Administration's (FDA) planned automated Import Support and Information System (ISIS). Our detailed responses to these questions begin on page 2.



As you know, FDA is developing ISIS to support its import enforcement staff and improve the efficiency and effectiveness of import operations. FDA plans to develop ISIS in stages. The basic system will be developed during the initial stage and is primarily intended to (1) track products that are wharf examined,[1] automatically detained, or sampled and tested for compliance with regulations; (2) maintain a historical data base; and (3) provide office automation capabilities. FDA has prepared a system design document outlining the initial stage and plans to enhance the system in later stages. FDA estimates fiscal year 1988 funding for ISIS to be $1.6 million for software development and computer hardware. Additional background information is included as appendix I.

In preparing its initial plans for ISIS, FDA had not followed some important automated systems development practices that are required by the Department of Health and Human Services (HHS). These practices are consistent with Federal Information Processing Standards. After we pointed out HHS' system development requirements to FDA in November 1987, it took some actions to better comply with them. However, in finalizing its plans to develop ISIS, FDA has not taken three important steps required by HHS. These required steps are aimed at increasing the probability that FDA will (1) competitively procure hardware and software that will achieve its functional requirements, (2) design and implement a system that will achieve its interface requirements, and (3) select the most appropriate system design to achieve its mission requirements.

[1] Field examinations conducted where the incoming shipments are stored to inspect products and scrutinize product labels.

FDA specified vendor-specific computer hardware and software that are not based on functional requirements. HHS' guidelines and other applicable regulations state that hardware and software specifications should be described in terms of what is functionally required of them. Therefore, there is an increased risk that FDA will inappropriately limit competition and procure hardware and software that will not meet its needs.

Although FDA recognized the need to interface ISIS with Customs' automated systems, FDA has decided to postpone identifying the interface requirements until after ISIS is operational. HHS' guidelines state that interface requirements should be identified and planned before systems are developed. As a result, there is an increased risk that ISIS will be unable to interface with Customs' systems.

FDA has not identified alternative system designs for management consideration. HHS' guidelines state that alternative system designs that satisfy functional requirements should be proposed for management consideration. Consequently, there is an increased risk that FDA will select a system that is not the most appropriate to meet its mission requirements.

We are recommending that the Secretary of HHS take steps to reduce the risk that ISIS may not satisfy mission needs (see p. 8).

We conducted our audit from September 1987 to June 1988. Our objectives, scope, and methodology are included in appendix II.

Responses to Chairman's Questions on the Development of ISIS

To what extent is FDA proceeding in accordance with generally accepted system development procedures and applicable regulations in the development of ISIS?

FDA has not completed some important system development steps as required in HHS' guidelines. System development life-cycle guidelines are commonly used methodologies that divide the automated system development process into distinct phases and allow periodic management review. According to Federal Information Processing Standards,[1] the life

[1] Federal Information Processing Standards Publication 64, Guidelines for Documentation of Computer Programs and Automated Data Systems for the Initiation Phase and Publication 38, Guidelines for Documentation of Computer Programs and Automated Data Systems, National Bureau of Standards, Department of Commerce.

cycle has three phases: (1) the project request,[1] feasibility study, and cost-benefit analysis (initiation phase); (2) the identification and analysis of user requirements, system design and specification, development, and testing (development phase); and (3) system implementation, operation, and maintenance (operation phase). HHS' system development guidelines, contained in HHS' Information Resources Management Manual, are consistent with Federal Information Processing Standards.

As part of the initial phase of ISIS, a feasibility study was issued in February 1987. Also, in February 1987, the Commissioner formed a task force to develop ISIS as recommended in the feasibility study. In November 1987 the task force issued a draft design document describing FDA requirements for and general design of the system. Currently, ISIS is in the second (development) phase.

On November 4, 1987, we asked FDA's task force officials whether they followed HHS' system development guidelines, as required in Part 2 of HHS' Information Resources Management Manual, or other system development guidelines. Task force officials said they were not aware of and did not follow HHS or other system development guidelines in identifying requirements and preparing the system design document. They said they planned to initiate action to contract for the acquisition and development of software and the acquisition of hardware as soon as the draft system design document was approved.

We analyzed the content of FDA's February 1987 feasibility study and November 1987 draft system design document using HHS' system development guidelines. While FDA had performed much of the initiation and development phase work required by HHS, our review showed that FDA had not performed some important analyses or identified some basic system requirements. FDA specified a particular make and model of hardware and software instead of specifying its requirements in functional terms. In addition, FDA did not identify performance objectives and requirements such as user response times, external interface requirements, effects on the current organization and operation, system failure contingencies, and alternative system design proposals.

On January 28, 1988, we discussed these matters with task force officials and FDA's Deputy Director, Office of Regulatory Resource Management, who oversees the task force. These officials generally agreed with

[1] A project request is a document prepared by a user organization to develop, procure, or modify automated data processing (ADP) support or operations.

the results of our analysis and stated that they had reviewed HHS' system development guidelines, taken some corrective actions, and revised the ISIS design document.

Our analysis of the revised draft design document showed that, since our November 1987 meeting, the task force had made progress to better identify FDA's ISIS requirements. However, the design document, approved in May 1988, still does not meet three HHS requirements.

First, the task force specified a particular make and model of hardware and software instead of specifying FDA's computer hardware and software requirements in functional terms, as required in HHS' Information Resources Management Manual. The functional requirements of ISIS do not show a unique need that would justify the specification of a particular hardware or software. We have no reason to believe that FDA's functional requirements cannot be accomplished by other available hardware and software.

The Federal Information Resources Management Regulations (41 CFR 201-11) require an agency's acquisition strategy to state user requirements in the least restrictive terms possible without compromising economy or efficiency. These regulations permit a make and model specification only when no other type of specification can satisfy the needs of the government. The use of a make and model specification must be formally justified. According to the Deputy Director of the Office of Regulatory Resource Management, the only justification prepared by the task force was the agency procurement request itself. The agency procurement request, which was submitted on March 7, 1988, through FDA for approval by HHS, did not include a justification of specific make and model. This increases the risk that FDA will inappropriately limit competition among potential vendors and procure hardware and software that will not meet its information processing work load and needs.

Second, the task force did not follow HHS' Information Resources Management Manual, which requires that interface requirements be identified and planned before systems are developed. As a result, there is an increased risk that FDA will develop and implement a system that will be unable or impractical to interface with Customs' systems.

Third, the task force proposed only one system design, instead of identifying alternatives from which to select the most appropriate automated system design. HHS' Information Resources Management Manual states

that alternative system designs to satisfy the functional requirements of the system should be proposed for management consideration. Exploring alternative designs reduces the risk that FDA will select a system design that is not the most appropriate to meet its mission requirements.

What assurance does FDA have that ISIS will interface with the U.S. Customs Service's automated systems and capture data on the volume and types of imported products subject to FDA regulation?

FDA has no assurance that ISIS will be able to interface with Customs' automated systems. HHS guidelines require identifying interface requirements before systems are developed. FDA's task force has recognized the need to identify and plan for FDA's interface requirements, but it has not adequately dealt with the issue. The task force is postponing these actions until after the basic ISIS system is developed and operational because FDA and Customs officials have been unable to agree on the specifics of an automated interface.

Postponing such action could jeopardize FDA's planned interface with Customs' systems in later stages of ISIS. The interface is intended to (1) provide two-way electronic communication among Customs, importers, and FDA; (2) electronically capture data on all import entries within FDA's jurisdiction; and (3) eliminate most of the paper transactions among FDA, Customs, and importers. Task force officials agreed that there may be problems when the interface is attempted at a later stage of ISIS.

Correspondence between Customs and FDA shows that officials recognize the need to agree on an automated interface, and have discussed developing it since at least 1984. However, they have not agreed on the details of an automated interface, officials said, because of different operating practices and needs of the agencies.

One problem cited is that Customs and FDA use different product coding schemes to classify imports. The agencies have not agreed on a coding scheme that would satisfy both because the different coding systems serve different needs. FDA's task force and Imports Operations Branch officials believe that the product codes in Customs' automated data bases do not give sufficient detail for FDA's needs and therefore would lessen the usefulness of an automated exchange of information from Customs' systems. For example, FDA officials need information, such as the type of packaging and size of container, to enforce FDA regulations.

This is not in the Customs data base. Also, some plastics, which are considered to be medical devices under FDA regulations, are not coded by Customs so that FDA can recognize them as such.

Another difference, cited by the Director of FDA's Import Operations Branch, is the need for FDA to collect data on all regulated imports. Customs collects data on only those imports above certain dollar limitations. In commenting on our report, Customs said it does collect data on entries below the dollar limitations when they are transmitted electronically from brokers.

ISIS and Customs' Automated Commercial System,[1] the system that processes import data provided by brokers, also has characteristics that increase the risk of problems with an interface. For example, FDA task force officials told us that if FDA asked Customs to detain a product of a specific importer at a specific port, Customs' Automated Commercial System would not direct the detainment message only to the port requested. Instead, on the basis of current automated procedures, the Automated Commercial System would send the detainment message to all ports. In commenting on our report, Customs said it has the ability, through other systems, to target a specific importer at a specific port if requested by FDA.

Does FDA plan to use ISIS to collect data on the volume and types of all FDA-regulated imported products?

As now planned, FDA will not collect, in ISIS, data on the volume and types of products of all FDA-regulated imports. ISIS is to collect data only for those imports that are wharf examined, automatically detained, or sampled by FDA, but not those that are released for entry into the country without further action. According to the Deputy Director of the Office of Regulatory Resource Management, this means that the ISIS historical data base will include information on only approximately 2 percent of the entries.

The ISIS feasibility study concluded that volume data on all imports would not be collected. Only information on entries sampled or automatically detained would be a part of the ISIS historical data base. This was done to keep FDA's data entry work load to a minimum, since no interface would be initially established with Customs or the brokers to

[1]A system that is intended to automate all of Customs' commercial operations into one integrated system.

receive data electronically. FDA's task force agreed with the study's conclusion. According to task force officials, FDA has no plans to collect total volume data in the initial stage of ISIS.

The collection of volume data by FDA was the subject of a prior GAO report[1] and testimony before the Congress.[2] In addition, a requirement to collect volume data on imported food products is contained in The Omnibus Trade and Competitiveness Act of 1988, signed into law on August 23, 1988.

In our September 1986 report, we found that many imported foods were not being sampled and tested by FDA for pesticide residues even though they were being imported into the United States year after year. We pointed out that FDA needs to improve the range of imported foods that are sampled. We also said that to assist in analyzing its commodity coverage and selecting foods to be sampled, FDA should prepare a comprehensive monitoring summary containing the following information: commodities being imported, country of origin, volume, number of samples taken, and number of violations.

In the December 1987 hearings before the Subcommittee on Health and the Environment, House Committee on Energy and Commerce, on H.R. 3504, an earlier bill, we testified in support of requiring the collection of volume data on imported foods. We said that collection of these data are necessary to provide a greater assurance that FDA's monitoring program is able to detect serious, recurring pesticide residue violations. However, FDA's Commissioner testified that the legislation was unnecessary because FDA already had plans to build ISIS to track the results of its sampling and testing program and implement the recommendations of FDA's Chemical Contaminants Data Project Workgroup. The workgroup recommended collecting more information on pesticides and other contaminants.

The trade act requires FDA to provide a summary of the volume of each type of imported food subject to FDA regulation that has an entry value over the threshold to be established by the HHS Secretary. The trade act also states that, to the extent feasible, information with respect to volumes of food products should be obtained from data bases of other federal agencies. The act requires the information to be summarized

[1] Pesticides: Better Sampling and Enforcement Needed on Imported Food (GAO/RCED-86-219, Sept. 26, 1986).

[2] H.R. 3504: Pesticide Monitoring Improvements Act (GAO/T-RCED-88-12, Dec. 14, 1987).

annually and made available to federal and state agencies and other interested persons.

The trade act requires FDA to collect volume data on food imports, but the act does not limit FDA to using ISIS as its only option. If FDA decides or is required to collect in ISIS such volume data, changes would be needed in the system design and statement of functional requirements. Without an automated interface with Customs, data entry would increase, and the required processing, storage, and telecommunications capacities of the new system would increase because the data base and number of input transactions would be much larger.

To what extent will ISIS be compatible with existing FDA systems such as the Laboratory Management System, including chemical contaminants data which are to be added to the Laboratory Management System, as suggested by the Chemical Contaminants Data Project Workgroup?

FDA's task force determined that ISIS and the Laboratory Management System are compatible and proposed that an interface be included in the initial stage of ISIS. Such an interface would provide ISIS users with access to chemical contaminants data through the Laboratory Management System.

After reviewing the ISIS design document and Laboratory Management System specifications, it appears that the proposed ISIS and the Laboratory Management System will be compatible. However, we cannot be certain that ISIS will be compatible with the Laboratory Management System or other FDA systems until the detailed design specifications for ISIS are developed and the system is tested.

Conclusions

FDA has not followed some of HHS' system development requirements and we have seen no indication that it plans to take action to comply with those requirements. If FDA does not comply with the requirements, it will increase its risks that the system may not satisfy mission requirements in a timely and effective manner.

Recommendations

We recommend that the Secretary of Health and Human Services take steps to ensure that the Food and Drug Administration complies with HHS' requirements to (1) identify and specify FDA's computer hardware and software requirements for ISIS in functional terms, rather than specifying vendor-specific computer hardware and software; (2) identify

FDA's requirements for an ISIS automated interface with Customs, and obtain an agreement on a plan to implement the automated interface; and (3) explore feasible alternative system designs to meet the functional requirements of ISIS.

Agency Comments and Our Evaluation

HHS' and Customs' comments, together with our evaluation, are contained in appendixes III and IV. See pages 17 and 27 for more details.

HHS did not agree with our first recommendation that FDA identify and specify its requirements in functional terms rather than in vendor-specific terms. HHS stated that a principal departmental strategy is to evolve existing systems in the direction of open architecture to ensure a more competitive environment. HHS believes, at this time, that FDA's extensive investment in its current equipment, commitment to a specific proprietary software package, need for hardware and software that is directly compatible with existing systems, and need to interface with existing information systems is very strong justification for specifying requirements in vendor-specific terms. HHS did not provide any analysis or justification to support its belief. As we state on page 4, the ISIS design document, the only existing documentation of requirements, does not show a unique need that would justify the specification of a particular hardware or software. HHS said that a justification to support the acquisition on specific make and model is being developed and will be approved before proceeding.

HHS concurred with our second recommendation and stated that FDA will continue to negotiate with Customs on unresolved problems and develop an automated interface that will be implemented as soon as practical.

HHS concurred with our third recommendation. HHS stated that FDA had explored alternative designs for ISIS and will now document those exploratory efforts.

Customs generally agreed with our conclusions and recommendations. We clarified two points suggested by Customs. (See p. 6.) Customs also said that as part of an ongoing effort to cooperate with FDA, it is implementing a work plan to assist FDA in developing a future interface.

As arranged with your office, unless you publicly announce its contents sooner, we plan no further distribution of this report until 20 days from the date of this letter. At that time, we will make copies available to FDA, Customs, and other interested parties upon request.

Sincerely yours,

Ralph V. Carlone

Ralph V. Carlone
Director

Contents

Abbreviations

ADP	automated data processing
DEC	Digital Equipment Corporation
FDA	Food and Drug Administration
GAO	General Accounting Office
GSA	General Services Administration
HHS	Department of Health and Human Services
IMTEC	Information Management and Technology Division
ISIS	Import Support and Information System

Background

FDA's overall mission is to protect the public from any domestic or imported food, drug, or health-related device that might threaten public health. The number of imports subject to FDA regulation has increased threefold since the mid-1970s, from 500,000 to over 1.6 million entries[1] as estimated by FDA for 1987.

Currently, FDA's import enforcement operations are largely accomplished without the daily support of automated systems. Some district offices have developed local historical data bases, but there is no automated system capability to share this information with other district offices or compile the data for nationwide oversight.

The FDA Commissioner has put a priority on improving import operations, including increased automated support. In February 1987, the Commissioner formed the National Import Data System Task Force, composed of three district compliance officers and a district director, who is chairman. The task force was to develop a new automated system as recommended in a contractor-prepared feasibility study[2] issued on February 18, 1987. In November 1987, the task force issued a draft design document for ISIS, which called for a system to provide up-to-date information to all field offices on imports that have been tested and identify trends and problems for products that do not meet FDA regulations. The design document was approved by FDA's Office of Regulatory Resource Management in May 1988. The task force prepared an agency procurement request to obtain authority to procure software development services.

The Deputy Director of the Office of Regulatory Resource Management stated that FDA is planning a software development contract, but that it would not be awarded until at least the fourth quarter of fiscal year 1988. He added that the first pilot test is scheduled for spring 1989. As of June 14, 1988, FDA had not purchased computer hardware or software development services for ISIS.

[1]FDA made this estimate on the basis of 1984 data in its document, "A Plan For Action, Phase II." In 1985, the definition of an entry changed from a product or group of products valued at $250 or more, to those valued at $1,000 or more.

[2]A feasibility study is a document that (1) analyzes automation objectives, requirements, and system concepts; (2) evaluates alternative approaches; and (3) chooses a proposed approach.

Objectives, Scope, and Methodology

Our objectives were to answer the Subcommittee's questions about the development of FDA's ISIS. The Subcommittee asked us to determine (1) to what extent FDA is proceeding with generally accepted computer system development procedures and applicable regulations; (2) what assurance FDA has that ISIS will interface with Customs' automated systems; (3) whether FDA plans to collect volume and type of product data on all imports in ISIS or through an automated interface with Customs; and (4) to what extent ISIS will be compatible with internal FDA systems, such as the Laboratory Management System, and include chemical contaminants data as recommended by the Chemical Contaminants Data Project Workgroup.

To determine to what extent FDA is proceeding in accordance with generally accepted computer system development procedures and applicable regulations, we interviewed members of the National Import Data System Task Force, and reviewed (1) the feasibility study for the automated import data system, (2) the ISIS design document revised as of May 1988, and (3) task force subgroup draft reports.

We compared the contents of these documents with system development guidelines contained in the HHS Information Resources Management Manual (November 1985), Federal Information Processing Standards Publications (FIPS PUBs 38, 64, 65, 73, 101, and 102), and one commercial methodology used in private industry. Since ISIS has not been identified as a major system under the definition of OMB Circular A-109, and is therefore not subject to the circular's provisions regarding the acquisition of major systems, we did not review FDA's adherence to these requirements. We discussed the results of our analysis with the Deputy Director of the Office of Regulatory Resource Management and import task force officials.

We reviewed the ISIS design document and correspondence between FDA and Customs, and interviewed FDA task force officials to determine what assurance FDA has that ISIS will interface with Customs' automated systems. We also reviewed the general design of Customs' automated systems (the Automated Commercial System and the Automated Broker Interface) and the data available to FDA through these Customs' systems, and interviewed Customs officials about the interface.

To determine if FDA will capture, in ISIS or through an interface with Customs, data on volume and type of imported products subject to FDA regulation, we reviewed the feasibility study and ISIS design document, and interviewed the Deputy Director of the Office of Regulatory

Resource Management and task force members. We analyzed draft bill H.R. 3504, "Pesticide Monitoring Improvements Act," and the trade bill, H.R. 4848, Subtitle G, "Pesticides Monitoring Improvements Act of 1988," which required FDA to collect and summarize volume data on all imports above a value established by HHS. The latter bill, entitled "The Omnibus Trade and Competitiveness Act of 1988," was signed into law on August 23, 1988.

To determine the extent to which ISIS will be compatible with other FDA systems, such as the Laboratory Management System, and include the recommendations of the Chemical Contaminants Data Project Workgroup, we reviewed the ISIS design document and the ISIS/Laboratory Management System interface subgroup draft report. We also interviewed the Deputy Director of the Office of Regulatory Resource Management and import task force members about the proposed interface.

We conducted our review from September 1987 to June 1988. We did not assess the need for ISIS or determine if its functional requirements were appropriately specified by FDA. We obtained agency comments from FDA and Customs and have incorporated them where appropriate. Our work was performed in accordance with generally accepted government auditing standards.

Comments From the Department of Health and Human Services

Note GAO comments supplementing those in the report text appear at the end of this appendix

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General

Washington, D.C. 20201

AUG 8 1988

Mr. Lawrence H. Thompson
Assistant Comptroller General
U.S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Thompson:

Enclosed are the Department's comments on your draft report, "ADP Systems: FDA Can Reduce Development Risks for Its Import Information System." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely yours,

Richard P. Kusserow
Inspector General

Enclosure

COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE GENERAL ACCOUNTING OFFICE'S DRAFT REPORT, "ADP SYSTEMS: FDA CAN REDUCE DEVELOPMENT RISKS FOR ITS IMPORT INFORMATION SYSTEM"

General Comments

See comment 1.

We appreciate the opportunity to review the draft report. As noted by GAO, the Food and Drug Administration (FDA) has made efforts to comply with the Department's guidelines for system development when the requirements were made known to Agency officials. Further efforts to comply are underway and will continue until all required documentation has been completed.

See comment 2.

While we believe that FDA's use of Digital Equipment Corporation (DEC) equipment is appropriate for the Import Support and Information System (ISIS), we also recognize the disadvantages of over-reliance on the products of a single vendor. When an application is locked in to a single product line there are often limitations on the variety of hardware and software available. Functionality and flexibility can also be limited, and prices can be higher than those that prevail in markets with multiple compatible vendors. For these and other reasons it is a principal strategy of our Department to evolve existing systems in the direction of open architectures and to establish portability platforms for major application systems. Following this strategy will ensure that future acquisitions to support ISIS will occur in a more competitive environment and there will be a broader variety of equipment and software from which to choose.

See comment 2.

Nevertheless, we remain convinced, at this time, that in implementing this system, FDA has a compelling need to procure computer equipment and software that is directly compatible with its existing equipment and software. All FDA field offices (22 district offices, six regional offices, and numerous resident posts) and the headquarters Office of Regional Operations currently use DEC equipment. The current plan for the ISIS system calls for procurement of additional computers to be assigned to districts having heavy import responsibilities and enhancement of the existing computers in districts dealing with a lower volume of imported products. Further, rapid communication with all districts and headquarters is essential if the challenge of dealing with an ever-increasing import workload on a national basis is to be met. The proposed DEC equipment is necessary to facilitate this communication.

See comment 3.

Prior to purchasing FDA's current DEC equipment, FDA conducted a thorough analysis of its requirements and the equipment and services available to meet those requirements. FDA's offices are widely dispersed across the Nation and each must be functionally independent while also having the ability to communicate quickly

among other offices as well as with headquarters. The FDA determined that a decentralized system that would place computers as close to the primary user as possible would best meet its needs. The DEC equipment was selected based on these and other relevant factors.

See comment 4

As discussed with GAO, FDA has a sizeable investment in DEC equipment, personnel training and expertise, and supporting software. We believe that it would not be cost effective and in the best interest of FDA to disrupt the current import operations to accommodate computer equipment and software that is not totally interchangeable with the existing computer and software system currently in operation at FDA's regional offices. FDA plans to utilize the new computer equipment as backup for the existing system as necessary. Further, we believe the added system reliability afforded by having interchangeable backups for FDA's current information systems, as well as ISIS, will strengthen and make more efficient the import product operation capabilities of FDA.

GAO Recommendation

We recommend that the Secretary of Health and Human Services take steps to ensure that the Food and Drug Administration comply with HHS's requirements to:

1. Identify and specify FDA's computer hardware and software requirements for ISIS in functional terms, rather than specifying vendor-specific computer hardware and software.

Department Comment

See comment 5

We do not concur. Subsequent to the GAO review, necessary approvals were obtained from the Office of the Secretary and the General Services Administration on both the equipment and the FDA ADP support services and proprietary software for the ISIS. Additionally, in accordance with HHS procurement regulations a justification(s) to support the acquisition on specific make and model basis is being developed and will be approved before proceeding.

See comment 5

As discussed above, the extensive investment in the DEC equipment, coupled with FDA's commitment to the ORACLE software, and the need to interface with existing information systems is very strong justification for being vendor-specific in detailing hardware and software requirements, particularly after having thoroughly justified the original investment in the DEC equipment.

See comment 6

Another consideration at this time is the need to proceed with bringing ISIS on-line as quickly as possible. FDA began its efforts to modernize import operations some time ago to rectify

an increasingly cumbersome approach to this very critical element of its public health mission. Some members of Congress and Committees have recognized the importance of implementing an up-to-date import operations system and have held numerous hearings focused on this issue.

See comment 6

We believe that to interrupt the process at this time to restructure hardware and software requirements in a more generic manner would further delay the acquisition of the much needed computer equipment which will significantly improve the FDA import information system.

GAO Recommendation

2. Identify FDA's requirements for an ISIS automated interface with Customs, and obtain an agreement on a plan to implement the automated interface.

Department Comment

See comment 7

We concur. FDA's requirements for interface with Customs have already been identified. Data requirements for an ISIS/Customs interface have been communicated to the Customs taskforce with whom FDA is working and will continue to work to determine how the required information can be exchanged. FDA has also met with representatives of the brokers' association to explore the possibility of interface among brokers, Customs, and FDA. The primary purpose of the ISIS system is to automate processing and disposition of imported products so FDA can increase its inspectional productivity and expand the percentage of FDA-regulated import products inspected prior to release in the United States market. We believe that in order to just maintain its current coverage of imported products, FDA must automate this critical function.

See comments 7 and 8.

As to obtaining an agreement with Customs, the design of ISIS is such that additional functions can readily be added without the need to either purchase new equipment or to reconfigure any software or applications. FDA will continue negotiations with Customs regarding the unresolved problems of incompatible product codes, volume data, and access to shipments falling below the Customs formal entry cutoff. A direct interface with Customs will be effected as soon as practical.

GAO Recommendation

3. Explore feasible alternative system designs to meet the functional requirements of ISIS.

See comment 9

Department Comment

We concur. Alternative systems designs have been explored, but not fully documented. FDA will complete documentation of those exploratory efforts.

The following are GAO's comments on a letter dated August 8, 1988, from the Department of Health and Human Services. The letter was transmitted by the Inspector General of HHS.

GAO Comments

1. HHS said that FDA made efforts to comply with HHS guidelines for system development once the requirements were made known to FDA officials. HHS stated that further efforts to comply are underway and will continue until all the required documentation is completed. We agree that this action should be taken.

2. HHS said that its principal strategy is to evolve existing systems in the direction of open architecture and to establish portability platforms for major application systems. According to HHS, following this strategy will ensure that future acquisitions to support ISIS will occur in a more competitive environment and there will be a broader variety of equipment and software from which to choose. HHS said, however, that regardless of its principal strategy, at this time, FDA has a compelling need to procure computer equipment and software that is directly compatible with its existing equipment and software, and the proposed Digital Equipment Corporation (DEC) equipment is needed to facilitate communication among the districts and headquarters.

We agree with HHS' stated strategy to evolve its systems to ensure a competitive environment. We believe, however, that FDA has not demonstrated a compelling need or justified its use of vendor-specific specifications for this procurement. HHS did not provide any analysis or justification to support its belief. As we state on page 4, the ISIS design document, the only existing documentation of requirements, does not show a unique need that would justify the specification of particular hardware or software. HHS said that a justification to support the acquisition on specific make and model is being developed and will be approved before proceeding. See our response under comment number 5 for a further discussion of this issue.

3. HHS stated that prior to purchasing its current DEC equipment, FDA conducted a thorough analysis of its requirements and the equipment and services available to meet its requirements. The DEC equipment was selected on the basis of these and other relevant factors.

The existing automated equipment was procured before ISIS was designed, and therefore the ISIS functional requirements were not considered as part of that procurement. Thus, we believe that the analysis of

requirements for the procurement of the existing DEC equipment is not adequate justification for this procurement for ISIS. This procurement should be based on the functional requirements of ISIS.

4. HHS said FDA has a sizable investment in DEC equipment, personnel training and expertise, and supporting software. HHS believes that it would not be cost effective and in the best interest of FDA to disrupt the current import operations to accommodate computer equipment and software that is not totally interchangeable with existing equipment and software. HHS said that the added system reliability afforded by interchangeable backups will strengthen and make more efficient the import product operation capabilities of FDA.

We realize that FDA has a sizable investment in personnel training and expertise on the existing systems that must be considered as a cost of procurement as provided for in the Federal Information Resources Management Regulations (41 CFR 201-11). As we discuss on page 4, FDA has not formally justified its make and model specifications, including demonstrating that less restrictive terms would compromise economy or efficiency.

5. HHS did not concur with our recommendation that FDA comply with HHS' requirements to identify and specify FDA's computer hardware and software requirements for ISIS in functional terms, rather than specifying vendor-specific computer hardware and software. HHS stated that, after our review, FDA had obtained approvals from the Office of the Secretary and the General Services Administration for both the equipment and the ADP support services and proprietary software for ISIS. HHS further stated that in accordance with its regulations, a justification to support the acquisition on specific make and model basis is being developed and will be approved before proceeding.

HHS cited the extensive investment in DEC equipment, FDA's commitment to ORACLE software, and the need to interface with existing information systems as very strong justification for being vendor-specific in detailing its hardware and software requirements.

We asked GSA officials to confirm whether GSA had granted approvals for the hardware and software for ISIS. GSA officials told us that they had approved the ADP support services and software procurement. They stated that for this procurement, FDA said it will contract with a qualified minority-owned and -operated small business certified under section 8(a) of the Small Business Act to provide the initial conceptual

design and implement a pilot test of ISIS. They also said the contractor, acting as the government's agent, will negotiate the best available price for the acquisition and, according to FDA, all associated procurements will be fully competitive.

The GSA officials stated they had not approved the hardware procurement. They said GSA received a letter from FDA stating that the hardware procurement for ISIS would be a sole-source contract under $1 million. According to the GSA officials, only sole-source procurements that exceed $1 million at HHS require GSA approval. In clarifying the HHS comments, an FDA official stated that the sole-source hardware procurement had been approved by HHS' Office of the Secretary but not by GSA.

We believe that FDA's investment in DEC equipment, its commitment to ORACLE, and the need to interface with existing systems are not sufficient reasons to use vendor-specific make and model specifications. At the time of our audit, FDA had not developed a justification for using make and model specifications. As we state on page 4, the functional requirements of ISIS do not show a unique need that would justify the specification of a particular hardware or software. Other types of hardware and software are capable of fulfilling the functional requirements and are compatible with existing DEC equipment. HHS said FDA will develop a justification to support the acquisition on specific make and model before proceeding with the procurement.

6. HHS said another consideration is that FDA needs to bring ISIS on-line as quickly as possible, and to interrupt the process at this time to restructure the hardware and software requirements would further delay obtaining much-needed computer equipment.

We disagree. The need to implement a system quickly is not sufficient reason to use make and model specifications. The Federal Information Resources Management Regulations (41 CFR 201-11) state that the lack of advance planning cannot be used as a basis for not conducting full and open competition. The regulations also state that, in order to ensure full and open competition, proper management activities must be accomplished before contract actions become imminent.

7. HHS concurred that FDA should identify its requirements for an ISIS automated interface with Customs, and obtain agreement on a plan to implement the automated interface. HHS stated that FDA has identified its interface requirements and has communicated its data requirements to

Customs. HHS also said that FDA has met with representatives of the brokers association to explore an interface. HHS said it believes that FDA must automate this critical function to maintain its current coverage of imported products. HHS said that the design of ISIS is such that additional functions can readily be added without the need to either purchase new equipment or to reconfigure any software applications.

We agree with HHS that a direct interface with Customs should be implemented. We believe that FDA has not adequately dealt with the ISIS interface issue. As we state on pages 5 and 6, the FDA task force has postponed identifying and planning for the interface requirements until after the basic ISIS system is operational because FDA and Customs officials have been unable to agree on the specifics of an automated interface. FDA officials also stated that the product code differences and the lack of data on imports below Customs' dollar threshold were unresolved and were obstacles to an interface. Unless the interface issues are resolved, FDA is jeopardizing its planned interface with Customs' systems in the later stages of ISIS and increasing the risk that the system may not satisfy mission requirements in a timely and effective manner.

8. HHS stated that FDA will continue negotiations with Customs regarding the unresolved interface problems and a direct interface will be effected as soon as practical.

We agree that continued negotiations between FDA and Customs are crucial to accomplishing this important interface. But, as we state on page 5, discussions have taken place since at least 1984 without an interface agreement. We believe that the interface plans must be completed to ensure that the systems will interface without unduly increasing risks that major changes in ISIS will be needed, and FDA can efficiently obtain all of the data it needs, when it is needed. We also noted that on page 1 of its July 21, 1988, letter (see app. IV), Customs states that it will in the near future be adopting an internationally set standard of product identification codes. According to Customs, once this new set of codes is adopted, there will be no incentive for Customs to recommend any change to its product identifiers to match FDA's. Therefore, Customs said, it believes it would be in FDA's best interests to explore the possible translation of its product codes into the international standard.

9. HHS concurred that FDA should explore feasible alternative system designs to meet the functional requirements of ISIS. HHS stated that FDA

explored alternative system designs, but did not fully document them. HHS said FDA will complete documentation of those exploratory efforts.

We agree that FDA should document the alternative system designs for ISIS, as required by the regulations. As noted on pages 4 and 5, during our audit we found no evidence that alternatives were explored, analyzed, documented, or presented for management consideration.

Comments From the Customs Service

Note GAO comments supplementing those in the report text appear at the end of this appendix

THE COMMISSIONER OF CUSTOMS

WASHINGTON, D.C.

MAN-1 C:D MJK

July 21, 1988

Dear Mr. Carlone:

See comment 1

We have reviewed your draft report on ADP SYSTEMS: FDA Can Reduce Development Risks For Its Import Information System. We believe the report is generally accurate in its conclusions and recommendations. However, some assertions in the report concerning Customs cooperation with FDA and Customs abilities to assist FDA in the performance of its mission need to be clarified.

See comment 1

Specifically, several issues touched upon on pages six and seven of the report require clarification.

The different product coding schemes used by the two agencies should not prevent an interface between the two automated systems. The specific name of the merchandise reflected in the FDA product code could be supplied to the broker/importer beforehand and entered as an additional data element on the appropriate document. Currently, steps are being taken to attempt some alignment, if possible, between the Customs National Import Specialists and the International Trade Commission with FDA.

See comment 1

It should also be recognized that Customs will be utilizing in the near future, an internationally set standard of product identification codes known as the Harmonized System. Once this is adopted, there will be no incentive for Customs to recommend any change to its product identifiers to match FDA's. It would be in FDA's best interests to explore the possible translation of its product codes into the Harmonized System.

See comment 1

Other additional data required for release of FDA merchandise are now being provided by the broker/importer and in some instances are provided using specialized software developed by companies servicing brokers and importers that import FDA merchandise. The collection and transmission of these additional FDA data elements from the invoice and other sources to ACS through ABI or data shown on the CF 7501 which will also be captured electronically should not hinder the development of an interface between Customs and FDA.

See comment 2.

In some instances, Customs does collect data for commercial merchandise imported with a value of less than $1,000 ($250 for certain textiles) for enforcement and duty collection purposes. Many commercial import entries below the $1,000 limit are presented on informal entries and are transmitted electronically through ABI. This information could easily be transmitted to FDA.

See comment 2

We do agree that at this time many informal entries are not captured within the system. The Census Bureau, which provides FDA with much of its import information, does not collect this information.

See comment 3.

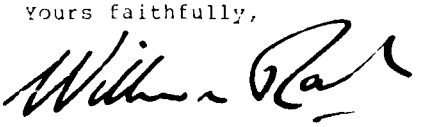
Finally, there are methods by which Customs can target and detain a product of a single importer at a single port. Not only does Customs have the ability to achieve targeting through national selectivity criteria but it can also limit it to a specific importer, product, or port through local criteria. This request can be passed by FDA to Customs either by memoranda or through an electronic mail application from an FDA personal computer to the Customs E-Mail system.

See comment 4.

For your information, Customs has developed, and is in the process of implementing, a work plan to assist FDA in a future interface. Customs has been working with FDA in the past and is assisting them in system development and implementing operational efficiencies for both agencies. We are confident of further cooperative efforts with FDA in the future.

Should any clarification of our response be required, please contact Mr. Matthew J. Krimski of the Day One Project on 566-8933.

Yours faithfully,



Mr. Ralph V. Carlone
Director, Information Management
and Technology Division
United States General Accounting Office
Washington, D.C. 20548

The following are GAO's comments on a letter dated July 21, 1988, from the U.S. Customs Service.

GAO Comments

1. The Commissioner of Customs said he believed the conclusions and recommendations were generally accurate. He added that several issues in the report required clarification. The Commissioner said the different product coding schemes used by the two agencies should not prevent an interface between the two automated systems. He said the specific merchandise name in FDA's code could be added as an additional data element; steps are being taken to attempt some alignment between the Customs National Import Specialists, International Trade Commission, and FDA; and other additional data required for FDA's release of merchandise will be captured by Customs. The Commissioner also noted that after Customs adopts an internationally set standard of codes (called the Harmonized System) to identify products, it will have no incentive to recommend changes to its product identifiers to match FDA's codes. In this regard, he said it would be in FDA's best interests to explore the use of this new code.

The Commissioner pointed out some ways that may help in the development of an automated interface with FDA. As we discuss, FDA and Customs have recognized the need to agree on an automated interface and have discussed developing one since at least 1984. One of the problems cited by officials is that Customs and FDA use different product coding schemes and have not agreed on a scheme that would satisfy both agencies. FDA's task force told us it was postponing further actions to identify and plan for FDA's interface requirements until after the basic ISIS system became operational.

As we state on page 5, postponing such action could jeopardize FDA's planned interface with Customs' systems in later stages of ISIS to (1) provide two-way electronic communication among Customs, importers, and FDA; (2) electronically capture data on all import entries within FDA's jurisdiction; and (3) eliminate most of the paper transactions among FDA, Customs, and importers. FDA task force officials agreed that there may be problems when the interface is attempted at a later stage of ISIS.

2. The Commissioner pointed out that, in some instances, Customs does collect data on commercial merchandise entries valued at below $1,000. He added that this information could easily be transmitted to FDA. The Commissioner did agree that many informal entries are not captured

within the system because the Census Bureau does not collect this information.

As we discuss on page 6, FDA said it needs to collect data on all FDA-regulated imports. Not receiving information on all entries below a certain dollar amount was cited as another problem affecting the resolution of an automated interface. As noted earlier, we believe these problems must be resolved and recommend that FDA identify its requirements for an automated interface with Customs, and obtain an agreement on a plan to implement the automated interface.

3. The Commissioner pointed out that there are methods that Customs can use to target and detain a product of a single importer at a specific port. He said FDA can request this of Customs, by memorandum or electronic mail application to Customs' electronic mail system.

As discussed on page 6, FDA task force officials cited this as a problem and told us that if FDA asked Customs to detain a product of a specific importer at a specific port, Customs' Automated Commercial System would not direct the detainment message only to the port requested.

We discussed the use of Customs' electronic mail system with a Customs official. According to the official, FDA could use any of several ways to have a message sent on the electronic mail system to any or all ports. Although the electronic mail system is not part of Customs' Automated Commercial System, FDA would have access to it through the automated interface with Customs, once it is developed.

4. The Commissioner said that Customs is implementing a work plan to assist FDA in a future interface. He said Customs has been working with FDA to develop the interface and he is confident of future cooperative efforts.

As we discuss on page 5, officials of the two agencies have been discussing the automated interface for a few years. We are not suggesting that the agencies have not cooperated with each other. Our purpose is to note that an agreement on the automated interface for the ISIS system has not yet been achieved.